White Paper

Fiber and Textile Innovations Pave the Way for Device Advancement

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DSM and Secant Medical break new medical ground with novel vascular textiles

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In February of this year, Overlake Medical Center in Seattle replaced a valve in the heart of an 87-year-old man in what was called a game-changing procedure.

The surgery was newsworthy because Overlake is one of only four hospitals in Washington to offer transcatheter aortic valve replacement (TAVR) to patients who have severe stenosis and are too high risk for traditional open heart surgery.

The procedure was groundbreaking because like so many emerging, minimally invasive treatments, TAVR is giving new hope to patients who until recently had few options for addressing a critical condition. Although expanding the pool of treatable patients isn't the only reason surgeons are gravitating toward minimally invasive surgery (MIS), it's changing the stakes for patients who would otherwise be left without surgical options.

A broad array of forces is driving the growing demand for MIS. According to Transparency Market Research of Albany, NY, the global market for MIS is expected to reach $50.6 billion by 2019. This growth is due to the increasing prevalence of chronic diseases such as arthritis, cancer and cardiovascular diseases; the aging of the global population, especially in developed countries; and the potential for lower healthcare costs resulting from less time in the OR, shorter recovery periods and less post-operative pain.

New Materials and Innovative Constructions Provide Foundation for Change

Much of the advancement of the MIS market can be attributed to technology developments in the materials science and textile processing industries, as evidenced by a partnership between biomaterials leader DSM and Secant Medical, a leading designer, developer and manufacturer of biomedical structures. The companies are using unique biomaterials, along with device component constructions that feature new property and performance characteristics. This combination enables previously inconceivable design developments, particularly in the cardiovascular and neurovascular fields.

Medical device companies targeting these fields focus on making biocompatible devices that are smaller, more durable, and offer low-profile delivery. Although it can be a challenge to meet all of these requirements, textiles are showing promising results. Just as tissue in the human body is fibrous, textile structures are formed with fibers and customized based on the biomimetic requirements of the application.

The properties of textiles are particularly conducive to the unique requirements of next-generation cardiovascular and neurovascular devices. In heart valve replacement devices such as those necessary for TAVR/TAVI procedures, textiles can help promote tissue ingrowth, provide anchoring and attachment of the implant, and prevent paravalvular leakage. In neurovascular applications, textiles have shape-memory properties, which enable bending or folding during delivery through a tight space, followed by expansion once implanted in the body.

In order for textile-based micro-devices to meet the requirements for new treatments in the vascular device field, they must be constructed with small yet strong biocompatible fibers. This maximizes performance within a confined space and offers a high safety profile for the implant. As a result, device designers and textile manufacturers are being increasingly challenged to push new limits in material selection.

A Grade Above

Secant Medical has partnered with DSM in the development of a range of leading-edge textiles and structures for vascular applications being brought to market by collaborating medical device companies. DSM's Dyneema Purity® fiber is renowned in the industry for being the only medical-grade ultra-high molecular weight polyethylene (UHMWPE) fiber that meets the market's demand for higher-performing implants that are stronger, smaller and last longer, according to Secant Medical.

Woven tubular biomedical structures engineered with regions of surface specialization elicit superior structural and performance properties for device design.

The material is stronger than medical steel, yet soft and highly pliable. It possesses ultra-high fatigue and abrasion resistance, excellent lubricity and near zero stretch, which is highly desirable in certain applications, such as non-compliant balloon catheters. DSM has consistently demonstrated a commitment to creating the fine denier fibers the vascular market requires. DSM's newly released Dyneema Purity® TG 10 dtex fiber is the finest medical-grade UHMWPE fiber on the market today, and like all other non-colored Dyneema Purity® fibers, this fiber is compliant to the ASTM F2848 Medical Grade UHMWPE yarn.

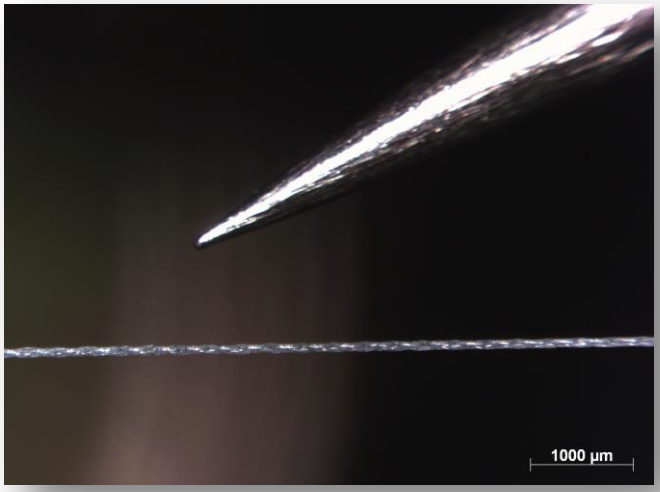
Equally important is the fact that Dyneema Purity® fiber is a biomaterial specifically developed for the design of applications in the human body during surgery or over the longer-term lifespan of a device; it is supported by a Master File on record with the FDA. Today, DSM

and Secant Medical are making a persuasive case for having the only true medical grade yarn used in device manufacturing.

Having access to more information about the raw components used in a product gives medical device companies a critical advantage as they navigate a highly-regulated industry. DSM's Master File provides the critical data that regulatory bodies need and enables companies to credibly assert that the appropriate due diligence was conducted during development. This additional data is helpful to both the commercialization process and risk mitigation.

Less is More

In addition to providing the only medical-grade UHMWPE yarn available, DSM offered Secant Medical and its partners another differentiator: the smallest fibers. When the partnership began in 2010, 25 dtex was the smallest. DSM recently launched an even finer denier, its Dyneema Purity® 10 dtex fiber, the world's thinnest medical fiber—thinner than a human hair. The fiber is four times stronger than polyester and is expected to be a key ingredient in the design and development of next-generation vascular devices.



Dyneema Purity® 10 dtex fiber

In the development of emerging neurovascular devices, for example, the emphasis is on the creation of tiny devices delivered via micro-catheters. The challenge is to develop super flexible textiles that can accommodate a low-profile delivery but are not compromised on strength. That's where textiles created with Dyneema Purity® 10 dtex fiber present an advantage. The fiber targets enhanced performance and a low profile, providing new options for applications for embolic filtration, clot removal and balloon angioplasty.

Cardiovascular applications are also benefitting from the use of textiles in minimally invasive approaches. Textile structures are an important component of heart valve replacement devices, because they promote tissue in-growth and enable a low-profile design, which is a key requirement for TAVR. They can also be customized based on pore size and elasticity.

The cardiovascular field is among the fastest growing therapeutic areas. The transcatheter heart valve segment (TAVI/TAVR) is expected to reach $1.5 billion by 2016, according to Millennium Research Group. Because of this anticipated market need, Secant Medical and DSM are targeting those segments in their application development work with medical device companies. These applications include:

- Skirts for TAVI heart valves (transcatheter aortic valve implantation). DSM's Dyneema Purity® 10 dtex fiber and Secant Medical's textile expertise enable low-profile delivery, high fatigue and abrasion resistance, low porosity with good suture ability, and bio-inertness.

- Skirts for AAA and TAA stent grafts (abdominal aortic aneurysm/thoracic aortic aneurysm). DSM's Dyneema Purity® 10 dtex fiber and Secant Medical's textile expertise enable low-profile fabrics to accommodate smaller catheters and enable safe contact with blood and vascular tissue.

Tapered bifurcated AAA stent graft fabric with unique weave pattern and shape designed to optimize flow dynamics.

Help Where It's Needed

Prior to the emerging devices like those being developed with the help of DSM and Secant Medical, high-risk and extreme-risk stenosis patients were not treatable. Delivering devices through a standard 21 French catheter is not optimal, because the patients are already fragile and compromised, and there is the potential for trauma associated with common devices through that particular sized catheter.

As the French size decreases, surgeons can treat fragile populations more effectively. Smaller size catheters reduce trauma at the incision site and can lower the risk of infection. The devices themselves must have better compaction capabilities while being more robust than most traditional micro-devices. The fabric component, when constructed from low-profile Dyneema Purity® 10 dtex fibers, can achieve these requirements by taking up less room. The softness, lubricity and strength of Dyneema Purity® 10 dtex fiber enables the development of structures that exhibit increased levels of compliance and allow for easier deployment in catheter-based procedures.

DSM's Dyneema Purity® 10 dtex fiber has unique properties and thus requires specialized expertise in processing. Secant Medical's legacy of material processing, along with its long record of success with the Dyneema Purity® fiber, makes it a trusted partner to medical device companies. As part of that commitment to quality, Secant Medical has implemented a unique process for handling the fiber, from the winding of the fiber, warping of beams, drawing and entering of the loom, to the actual weaving of the fiber.

Reaching New Frontiers
This same attention to detail characterizes how both Secant Medical and DSM approach client engagements for device component design. They believe in collaboration between Secant Medical, DSM and the medical device client with a focus on the ultimate end-use application to best determine how the fiber should be processed and constructed.

Secant Medical has a 70-year history of making implantable structures for the body. Its engineering team has created an Integrated Product Development Process, a development cycle that spans every step from conception and feasibility through qualification, validation, commercialization, and next-generation design.

Collaborating with DSM has made Secant Medical a trusted specialist in converting Dyneema Purity® fiber into a variety of textile structures. DSM is the worldwide leader in UHMWPE fiber manufacturing for medical applications and Secant Medical sees DSM as a partner of choice for this unique raw material. The collaborative engineering approach that DSM ascribes to has been beneficial to delivering high value to Secant Medical's clients.

DSM remains committed to providing biomaterials to medical device manufacturers to create products that enable better outcomes and to pioneer the minimally invasive devices that will help achieve that goal.

Dyneema Purity® fiber will be supplied from DSM's plant in Greenville, NC. The ISO 13485:2003 certified facility is the only plant of its kind dedicated solely to the production of medical-grade fiber. Non-colored Dyneema Purity® fibers are compliant to ASTM standard F2848-10 entitled "Standard specification for Medical-grade Ultra-high Molecular Weight Polyethylene yarns."
